UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,944	11/12/1999	MICHAEL WILLIAM STEWART	T57005US	1063

25534 7590 05/20/2002

CAHN & SAMUELS LLP
2000 P STREET NW
SUITE 200
WASHINGTON, DC 20036

EXAMINER	
DECLOUX, AMY M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/438,944	Stewart, M. et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 11, 2002*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *12, 14, 17, 18, and 29-39* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *12, 14, 17, 18, and 29-39* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment , filed 3/11/2002 (Paper No. 21) is acknowledged and has been entered.

2. Applicant's amendment of the first line of the specification to update the status (and relationship) of the priority documents is acknowledged.

3. The rejections of record can be found in the previous Office Action, mailed 1-20-02 (Paper No. 20). In view of applicant's amendments, **the outstanding 112 first paragraph rejection has rejections have been withdrawn, however new grounds of rejection have been applied.**

NEW GROUNDS OF REJECTION

4. The following is a quotation of the second paragraph of 35 U.S.C.112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

5. Claims 12, 14, 17-18 and 29-39 are rejected under *35 U.S.C. § 112*, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 12, 14, 17-18 and 29-39 are indefinite in the recitation in claim 12 of "administering a second component" because it is not clear what the first component is. Substituting the word "agent " would overcome this rejection.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 12-14, 17-21 and 29-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of inducing a thrombus in vivo comprising administering a binding agent having a first component for binding the binding agent to a pre-selected site; administering a second component, said second component specifically binds platelets, and allowing the second component to bind the

binding agent; binding platelets on the second component; inducing activation of the platelets and thereby allowing a thrombus to form.

However, it is noted that independent claim 12 recites that the second component binds platelets, and therefore it is not clear how the recited method allows the second component to bind to the binding agent, as recited in line 5.

Claims 14 and 33, which depend on claim 12, recite that the binding agent is an antibody (claim 14) and that the antibody can further comprise a biotin ligand (claim 33). However, it is not clear how the recited method allows the second component to bind to the binding agent,

Claim 12 and dependent claims 17 and 36, respectively, recite that the second component comprises von Willebrand factor, and that the second component is von Willebrand factor conjugated with a ligand. However, it is not clear how the recited method allows the second component to bind to the binding agent.

Claim 12 and dependent claim 18 recite that the first component or the second component or both comprises biotin, homophyllic peptides and human Fc fragments. With the exception of wherein both components bare homophyllic peptides or human Fc fragments containing the disulphide linkages. Other than these exceptions, it is not clear how the recited method allows the second component to bind to the first component.

Claims 29-32, which depend on claim 12, recite that the preselected site comprises subendothelium, tumor associated antigen, tumor specific antigen and hyperplastic tissue, respectively. However, as noted for independent claim 12, it is not clear how the recited method allows the second component to bind to the binding agent.

Claim 34 recites the method of claim 12 wherein allowing the second component to bind to the binding agent comprises administering an anti-ligand that specifically binds the binding agent. However, it is noted that there is no recitation that the anti-ligand binds the second component. Therefore, it is not clear how administering an anti-ligand that binds the binding agent but is not recited as binding the second component, allows the second component to bind to the binding agent.

Claim 35 depends on claims 34 and 12 and recites said method wherein the anti-ligand is selected from the group consisting of avidin, streptavidin, neutravidin, and derivatives and analogs thereof. However, as noted that there is no recitation that the anti-ligand binds the second component. Therefore, it is not clear how administering an anti-igand that binds the binding agent but is not recited as binding the second component, allows the second component to bind to the binding agent.

Claim 37 depends on claims 34 and 12 and recites said method wherein the second component is von Willebrand factor conjugated with a ligand . However, there is no recitation that the anti-ligand recited in claim 34 binds the vonWillebrand factor conjugated with ligand. Therefore, it is not clear how administering an anti-ligand that binds the binding agent but is not recited as binding the ligand conjugated to von Willebrand factor, allows the second component to bind to the binding agent.

Claim 38 depends on claims 37, 34 and 12, and recites said method wherein the second component is von Willebrand factor conjugated with biotin. However, there is no recitation that the anti-ligand recited in claim 34 binds the vonWillebrand factor conjugated with ligand. Therefore, it is not clear how administering an anti-ligand that binds the binding agent but is not recited as binding the ligand conjugated to von Willebrand factor, allows the second component to bind to the binding agent. Therefore, it would require undue experimentation for one of skill in the art to predict which combination of innumerable ligands, anti-ligands, binding agents would be effective in a method of inducing a thrombus in vivo.

NOTE: It does appear that applicant has support for claims which combine the limitations of claims 35, 38 and one of claims 30-32, 33, 14 (wherein claim 14 recites an antibody or an antigen binding fragments thereof,) and 12, as illustrated by the experiments in Applicant's declaration filed 11-20-01.

8. Claims 12-14, 17-21 and 29-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims are drawn to a method of inducing a thrombus in vivo comprising administering a binding agent having a first component for binding the binding agent to a pre-selected site; administering a second component, said second component specifically binds platelets, and allowing the second component to bind the binding agent; binding platelets on the second component; inducing activation of the platelets and thereby allowing a thrombus to form.

However, the instant specification provides insufficient written description regarding the innumerable ligands, anti-ligands, binding agents encompassed by the instant claims, because one of skill in the art could not visualize a method comprising an effective combination of the recited innumerable ligands, anti-ligands, binding agents, that would be effective in a method of clot formation in vivo as recited in the instant claims, with out further description from the specification, with the exception of a method comprising one specific combination. Specifically, that combination, as illustrated in applicant's declaration filed 11-20-01, encompasses a binding agent comprising an biotin conjugated antibody to a tumor specific or tumor associated antigen, a second agent comprising vWF conjugated to biotin and the step of administering avidin as an anti-ligand. Under Vas-Cath, Inc. v. Mahurkar , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. See MPEP 2163.01.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640,
May 20, 2002

Patrick Nolan, Ph.D.
Primary Patent Examiner,